Applicants respectfully traverse these rejections as presented, and request reconsideration.

Rejections Under 35 U.S.C. §112

The Examiner has objected to the recitation of the limitation "mechanical actuator" in Claims 54 and 55. These claims have been amended to recite a mechanism which is "mechanically actuated" (Claim 54) and wherein the "mechanical actuation" automated (Claim 55). Applicants believe these amendments overcome the objections, are request withdrawal of the same.

Rejections Under 35 U.S.C. §102(b)

The Examiner has rejected Claims 1-3, 14-17, 34-36 and 46-47 as anticipated by Granzow. The December 6, 2001, Office Action states that:

> "Granzow et al. *inherently* discloses the same method and system for sterilizing and adjoining two ends of a tube exposing the ends to radiant energy for a certain period of time." [Emphasis added]

Further, the Examiner cites Granzow for teaching the utilization of radio frequency, laser energy or the like to melt opaque wall sections, thereby fusing them together and forming an aperture (column 2, lines 31-41 and column 4, lines 24-41). Applicants respectfully traverse this rejection, specifically with respect to the Examiner's invocation of the inherency doctrine.

Granzow is directed to a method of forming a connection between two sealed conduits using radiant energy which is capable of passing through a transparent housing (column 2, lines 8-16). Granzow teaches the use of visible, infrared, ultraviolet, or radio frequency sources for radiant energy (column 2, lines 32-33). Focused infrared radiant energy is preferred (column 2, lines 38-39). Housings made of a transparent, high melting plastic material, such as a polycarbonate material called Lexan, are necessary for the practice of the Granzow invention. An opaque disc is situated within the housing of each component (column 3, lines 39-40). The housings are connected together before being subjected to the sterilizing radiation (column 3,

lines 55-57). The disc is melted by the radiant energy to simultaneously create a pathway and seal the housings together (column 3, lines 58-68).

The presently rejected Claim 1 requires "preparing the end of each component to be joined *while* exposed to the active sterile field." Further, Claim 1 requires "joining the prepared ends together *while* exposed to the active sterile field." Claims 2-3 and 14-17 depend from Claim 1 and, therefore, include such limitations as well. The Examiner has apparently overlooked the scope of these two limitations. In the brief discussion provided by the Office Action, neither limitation is addressed.

As to Claim 34, the claimed method is limited to "bringing the prepared ends into contact with each other *while* in the active sterile field." Claims 35 and 36 depend from Claim 34 and, therefore, include such a limitation as well. This element is not discussed by the Examiner, nor is it taught by the Granzow reference.

With respect to Claim 46, the claimed system requires "a mechanism which brings the opened ends into aligned contact with each other *while* in the active sterile field." Claim 47, while also so limited by virtue of its dependence form Claim 46, further adds "wherein the active sterile field is created by a low voltage electron beam instrument." Granzow provides no teaching on aligning contact within the sterile field, nor on the use of electron beam sterilization.

In order for a reference to act as a § 102 bar to patentability, the reference must teach each and every element of the claimed invention. Kalman v. Kimberly-Clark Corp., 713 F.2d 760, 771 (Fed. Cir. 1983). Without the required teaching of "each and every element" as set forth in the claims, it is improper for the Examiner to continue such rejections under §102(b).

In the present instance, Granzow lacks the "each and every element" correspondence necessary to maintain a § 102(b) rejection because it does not teach the joining, contacting, or alignment of the component ends *while* in the active sterile field. In fact, Granzow teaches the exact opposite procedure, which is connecting the ends together before brining them within a radiating energy. The referenced limitation is required, in some form, by all the pending claims

of the present application. Therefore, Applicants respectfully request reconsideration of the claims, and withdrawal of the § 102(b) rejection at the Examiner's earliest convenience.

Inherency Argument:

Regarding the Examiner's (perhaps unintentional) invocation of the inherency doctrine, the Applicants strongly request withdrawal of this improper argument.

The Examiner's rejection of the pending claims is inappropriate because: 1) the Examiner has misapplied the inherency argument in view of the Granzow reference; 2) even if the argument were proper, the claimed steps do not flow from the teachings of the prior art; and 3) even if the argument were proper, the method for effecting sterilization in Granzow is not the same as the claimed invention.

First, inherency, or inherent teachings by prior art may arise in both the context of anticipation under §102, or obviousness under §103. In re Napier, 55 F.3d 610, 613, 34 USPQ2d 1782, 1784 (Fed. Cir. 1995). However, it is the claiming of a new use, new function, or unknown property which is inherently present in the prior art, that the inherency concept will defeat. See In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). Where the applicant claims a composition in terms of a function, property or characteristic and *the composition of the prior art is the same as that of the claim* but *the function* is not explicitly disclosed by the reference, the rejection for inherency under 102 or 103 is proper. In re Best at 1255, n.4 (Emphasis added). The same rationale may also apply to product, apparatus, and process claims claimed in terms of *function, property or characteristics*. See M.P.E.P. §2112 (Emphasis added).

In the present case, a method having the step of joining ends together while exposed to the active sterile field is claimed. The claimed function, property or characteristic of this step is for sterile joining of the components. In order to be a proper inherency rejection the prior art must teach the step of joining ends within an active sterile field, but possibly to achieve a different function, property or characteristic. For instance, joining the ends within an active sterile field to provide improved rigidity in the tubing connection. The inherency argument does

not allow the insertion of undisclosed elements into the prior art to form the basis of a rejection. In rejecting Claim 1-3, 14-17, 34-36 and 46-47 in view of Granzow by stating that it "inherently discloses the same method and system for sterilizing and adjoining two ends of a tube," the Examiner has added an undisclosed element (step) as well as its function to the Granzow reference—i.e., *while* exposed to the active sterile field. Therefore, the Examiner's rejection is improper and should be reversed.

Second, Granzow does not disclose the step of preparing the end of each component to be joined while exposed to the active sterile field. The preparing step does not inherently flow from what is disclosed in Granzow. To support an anticipation rejection based on inherency, the Examiner must provide factual and technical grounds establishing that the inherent feature necessarily flows from the teachings in the prior art. The Examiner has made no such showing. Granzow does not have any reason to prepare or join the tubing ends in such a sterile field because it uses a penetrating sterilization energy. With this penetrating sterilization of the tubing ends there is no need to perform such tasks within a sterile field. Further, if there is not sufficient teaching or reason to prepare the tubing ends then such cannot logically flow from the teaching of the prior art. Thus, Granzow does not anticipate Claim 1-3, 14-17, 34-36 and 46-47.

Finally, the method of sterilization is very different than that of the present invention. Granzow uses an opaque disc of material which is melted at about 200° C by radiant energy, thereby opening a passageway. Any bacteria on the discs are killed by the heat and trapped in the rehardening of the melt (col. 4, lines 1-5). The radiant energy taught in the only example disclosed by Granzow is focused and centered on the discs (col. 3, lines 59-64). The present invention uses a sterile field which is created to form an area for manipulating the pre-sterilized tubing ends within. These methods are very different. Therefore, the Examiner's inherency rejection is inappropriate and should be withdrawn.

Rejections under 35 U.S.C. §103(a)

The Examiner has rejected Claims 4-7, 37-40 and 48-49 as unpatentable over Granzow in view of Wakalopulos, and Claims 8-13, 41-45 and 50-56 over Granzow in view of Caputo. Applicants respectfully traverse these rejections and request reconsideration.

Wakalopulos is directed to an electron beam array for curing thin coatings. Nowhere within this reference does it teach the use for sterilization. The Examiner has pointed to no such teaching.

Caputo is directed to a plasma sterilization process and apparatus using a pulsed treatment with a vaporized antimicrobial agent to kill microorganisms on an article. The Examiner has relied on Caputo for teaching only gas treatment, UV and ozone exposure, and use of a CPU for automation. The Examiner has not pointed to any motivation to combine this reference with Granzow. Because Granzow requires the radiant energy to pass through the transparent housing to melt the disc, how would the use of gas treatment or ozone accomplish this task? The Examiner has provided no explanation of how this would be obvious to one skilled in the art.

In order to support a conclusion that a claim is directed to obvious subject matter, the cited references must impliedly suggest the invention ***described by the claim***, or the Examiner must present a convincing line of reasoning as to why an artisan would have found ***the claimed invention*** obvious in light of the teachings of the cited references. See Ex Parte Clapp, 227 U.S.P.Q. 972 (PTO Bd. App. 1985). "[T]he mere fact that the prior art could be so modified would not have made the modification obvious unless the prior art suggested the desirability of the modification." In re Laskowski et. al., 10 U.S.P.Q. 2d 1397, 1398, (Fed. Cir. 1989), citing, In re Gordon, 221 U.S.P.Q. 1125, 1127 (Fed. Cir. 1984). In discussing the mandate of 35 U.S.C. §103, the Federal Circuit holds "it is the invention as a whole that must be considered in obviousness determinations. The invention as a whole embraces the structure, its properties *and the problem it solves.*"[Emphasis added]. In re Wright, 6 U.S.P.Q. 2d 1959 (Fed. Cir. 1988). It is not enough to just find components in the prior art, as the Examiner has done here.

On that point, the Federal Circuit has noted:

> [I]t is impermissible to use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious . . . . [o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.

In re Fritch, 972 F.2d 1260, 1266, 23 USPQ2d 1780, 1784 (Fed. Cir. 1992).

Unless the references suggest the particular combination themselves, they cannot show the actual invention was obvious. *In re Mahurkar Patent Litigation*, 831 F.Supp. 1354, 1374, 28 USPQ2d 1801, 1817 (N.D. Ill. 1993). The decomposition of an invention "into its constituent elements, finding each element in the prior art, and then claiming that it is easy to reassemble these elements into the invention, is a forbidden *ex post* analysis." *Id.*

In the present case the Examiner has merely provided the "forbidden *ex post* analysis" by piecing together two references disclosing constituent elements of the present invention without any motivation to do so—other than that provided by the present application. The Examiner has given no weight to the claimed limitation of carrying on the manipulation while exposed to the active sterile field, though such a recitation individually distinguishes the present invention over the prior art.

The Examiner has given no thought to how one might combine the teaching of Granzow with the teaching of Caputo to accomplish the invention of this application. Instead, the Examiner has merely referenced component elements which are discussed in the cited references. Components or limitations which were not discussed by the references were given no weight by the Examiner.

For these reasons, Applicants request reconsideration of Claims 4-7, 37-40 and 48-49, as well as Claims 8-13, 41-45 and 50-56. All pending claims should now be considered allowable, and notice to that effect is earnestly sought.

CONCLUSION

In view of the amendments overcoming the §112 rejections, and the remarks above directed to the §§ 102(b) and 103(a) rejections, Applicants submit that the present application is in condition for allowance. Applicants respectfully request the Examiner to withdraw the rejections and allow the pending claims to issue. If any informalities remain which can be corrected by Examiner's Amendment, the examiner is requested to phone the undersigned attorney.

The Commissioner is authorized to charge any fees associated with this Amendment to Deposit Account No. 23-0280.

Respectfully submitted,

Date: March 5, 2001

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Sarah J. Goodnight (117084.1)

ATTACHMENT

Claim 54 (amended). The system of claim 46, wherein the mechanism which brings the opened ends into contact [comprises at least one] is mechanically [actuator] actuated.

Claim 55 (amended). The system of claim 54, wherein the [at least one] mechanical [actuator] actuation is automated.